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GROUP 1800

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

VISHVA M. DIXIT et al.

Serial No.: 08/443,982

Group Art Unit: 1803

Filing Date: May 18, 1995

Examiner: Unassigned

Title: METHODS AND COMPOSITIONS
FOR REGULATING FAS-
ASSOCIATED APOPTOSIS

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INFORMATION DISCLOSURE

STATEMENT UNDER 37 CFR § 1.97

Assistant Commissioner
for Patents
Washington, D.C. 20231

Dear Sir:

The references listed below, which may be material to the examination of the above-identified application, were disclosed in an Information Disclosure Statement dated November 16, 1995, directed to the pending parent application Serial Number 08/416,379 (filed 04/03/95). Copies of the references were also previously included; therefore, copies are not submitted herewith. This protocol conforms with 37 C.F.R. § 1.97 and MPEP 609 (A)(2). The Examiner is respectfully requested to make this information of record in the application. The references include:

Vaux et al., "An evolutionary perspective on apoptosis" Cell (1994) 76:777-779.

Ellis et al., "Mechanisms and functions of cell death" Ann. Rev. Cell Biol. (1991) 7:663-698.

Tomei et al., "Apoptosis: The Molecular Basis of Cell Death" Current Communications in Cell & Molecular Biology 3 (1991) Cold Spring Harbor Press, New York. A title page and table of contents were previously enclosed.

Tomei et al., "Apoptosis II: The Molecular Basis of Cell Death" Current Communications in Cell & Molecular Biology 8 (1994) Cold Spring Harbor Press, New York. A title page and table of contents were previously enclosed.

Duvall et al., "Death and the cell" Immunol. Today (1986) 7:115-119.

Cohen, "Apoptosis" Immunol. Today (1993) 14:126-130.

Brunner et al., "Cell-autonomous Fas (CD95)/Fas-ligand interaction mediates activation-induced apoptosis in T-cell hybridomas" Nature (1995) 373:441-444.

Dhein et al., "Autocrine T-cell suicide mediated by APO-1/(Fas/CD95)" Nature (1995) 373:438-441.

Ju et al., "Fas(CD95)/FasL interactions required for programmed cell death after T-cell activation" Nature (1995) 373:444-448.

Itoh et al., "The polypeptide encoded by the cDNA for human cell surface antigen Fas can mediate apoptosis" Cell (1991) 66:233-243.

Tewari et al., "Fas- and tumor necrosis factor-induced apoptosis is inhibited by the poxvirus crmA gene product" J. Biol. Chem. (1995) 270:3255-3260.

Yuan et al., "The *C. elegans* cell death gene *ced-3* encodes a protein similar to mammalian interleukin-1 β -converting enzyme" Cell (1993) 75:641-652.

Cerretti et al., "Molecular cloning of the interleukin-1 β converting enzyme" Science (1992) 256:97-100.

Thornberry et al., "A novel heterodimeric cysteine protease is required for interleukin-1 β processing in monocytes" Nature (1992) 356:768-774.

Miura et al., "Induction of apoptosis in fibroblasts by IL-1 β -converting enzyme, a mammalian homolog of the *C. elegans* cell death gene *ced-3*" Cell (1993) 75:653-660.

Baglioni, "Mechanisms of cytotoxicity, cytolysis, and growth stimulation by TNF" Tumor Necrosis Factors. The Molecules and Their Emerging Role in Medicine (1992) B. Beutler, M.D., ed., Raven Press, New York. A title page and table of contents were previously enclosed.

Yonehara et al., "A cell-killing monoclonal antibody (Anti-Fas) to a cell surface antigen co-downregulated with the receptor of tumor necrosis factor" J. Exp. Med. (1989) 169:1747-1756.

Trauth et al., "Monoclonal antibody-mediated tumor regression by induction of apoptosis" Science (1989) 245:301-305.

Watanabe-Fukunaga et al., "Lymphoproliferation disorder in mice explained by defects in Fas antigen that mediates apoptosis" Nature (1992) 356:314-317.

Tartaglia et al., "Two TNF receptors" Immunol. Today (1992) 13:151-153.

Boldin et al., "Self-association of the 'death domains' of the p55 tumor necrosis factor (TNF) receptor and Fas/AP01 prompts signaling for TNF and Fas/AP01 effects" J. Biol. Chem. (1995) 270:387-391.

Song, "Aggregation of the intracellular domain of the Type I tumor necrosis factor receptor defined by the two-hybrid system" J. Biol. Chem. (1994) 269:22492-22495.

Itoh et al., "A novel protein domain required for apoptosis" J. Biol. Chem. (1993) 268:10932-10937.

Bordignon et al., "Retroviral vector-mediated high-efficiency expression of adenosine deaminase (ADA) in hematopoietic long-term cultures of ADA-deficient marrow cells" Proc. Natl. Acad. Sci. USA (1989) 86:6748-6752.

Culver et al., "Lymphocytes as cellular vehicles for gene therapy in mouse and man" Proc. Natl. Acad. Sci. USA (1991) 88:3155-3159.

Rill et al., "An approach for the analysis of relapse and marrow reconstitution after autologous marrow transplantation using retrovirus-mediated gene transfer" Blood (1992) 79:2694-2700.

Anderson, "Human gene therapy" Science (1992) 256:808-813.

Steplewski et al., "Isolation and characterization of anti-monosialoganglioside monoclonal antibody 19-9 class-switch variants" Proc. Natl. Acad. Sci. USA (1985) 82:8653-8657.

Spira et al., "The identification of monoclonal class switch variants by Sib selection and an ELISA assay" J. Immunol. Meth. (1984) 74:307-315.

Oi et al., "Chimeric antibodies" BioTechniques (1986) 4:214-221.

Herlyn et al., "Anti-idiotypic antibodies bear the internal image of a human tumor antigen" Science (1986) 232:100-102.

Spriggs et al., "Tumor necrosis factor expression in human epithelial tumor cell lines" J. Clin. Invest. (1988) 81:455-460.

Watanabe-Fukunaga et al., "The cDNA structure, expression, and chromosomal assignment of the mouse Fas antigen" J. Immun. (1992) 148:1274-1279.

Owen-Schaub et al., "Anti-Fas on nonhematopoietic tumors: Levels of Fas/APO-1 and bcl-2 are not predictive of biological responsiveness" Cancer Res. (1994) 54:1580-1586.

Opipari, Jr. et al., "The A20 zinc finger protein protects cells from tumor necrosis factor cytotoxicity" J. Biol. Chem. (1992) 267:12424-12427.

Lum et al., "Coactivation with anti-CD28 monoclonal antibody enhances anti-CD3 monoclonal antibody-induced proliferation and IL-2 synthesis in T cells from autologous bone marrow transplant recipients" Bone Marrow Transplantation (1993) 12:565-571.

Hu et al., "A novel RING finger protein interacts with the cytoplasmic domain of CD40" J. Biol Chem. (1994) 269:30069-30072.

Higuchi et al., "A general method of *in vitro* preparation and specific mutagenesis of DNA fragments: study of protein and DNA interactions" Nucl. Acids Res. (1988) 16:7351-7367.

Ron et al., "pGSTag - a versatile bacterial expression plasmid for enzymatic labeling of recombinant proteins" BioTechniques (1992) 13:866-869.

Studier, "Use of bacteriophage T7 lysozyme to improve an inducible T7 expression system" J. Mol. Biol. (1991) 219:37-44.

Harper et al., "The p21 Cdk-interacting protein Cip1 is a potent inhibitor of G1 cyclin-dependent kinases" Cell (1993) 75:805-816.

O'Rourke et al., "Thrombospondin 1 and Thrombospondin 2 are expressed as both homo- and heterotrimers" J. Biol. Chem. (1992) 267:24921-24924.

Peters et al., "Ankyrins: Structure and function in normal cells and hereditary spherocytes" Seminars in Hematol. (1993) 30:85-118.

Clement et al., "Fas and tumor necrosis factor receptor-mediated cell death: Similarities and distinctions" J. Exp. Med. (1994) 180:557-567.

The following references may also be material to the above-identified application. Copies are included herewith. The Examiner is requested to make these references of record in the application. The references include:

Boldin et al., "A novel protein that interacts with the death domain of FAS/APO1 contains a sequence motif related to the death domain" J. Biol. Chem. (1995) 270:7795-7798.

Golstein et al., "Homology between reaper and the cell death domains of FAS and TNFR1" Cell (1995) 81:185-186.

This Information Disclosure Statement is submitted before receipt of the first Office Action on Merits. Therefore, the applicants believe that no fee is due. However, the Commissioner is hereby authorized to charge any fees which may be required by this paper to Deposit Account Number 03-1952.

Applicants would appreciate the Examiner's initialling and returning the Form PTO-1449, indicating that the references have indeed been considered and made of record herein.

PATENT
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This Information Disclosure Statement under 37 CFR § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

Respectfully submitted,

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Date: *January 30, 1996*

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